

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference BWY-005.25	<b>FOR FURTHER ACTION</b>	See item 4 below
International application No. PCT/US2004/021247	International filing date ( <i>day/month/year</i> ) 02 July 2004 (02.07.2004)	Priority date ( <i>day/month/year</i> ) 11 July 2003 (11.07.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant THE BRIGHAM AND WOMEN'S HOSPITAL, INC.		

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 <i>bis</i> .1(a).																								
2.	This REPORT consists of a total of 4 sheets, including this cover sheet.  In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.																								
3.	<p>This report contains indications relating to the following items:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 20%;">Box No. I</td> <td style="width: 70%;">Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input type="checkbox"/>	Box No. VIII	Certain observations on the international application
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4.	The International Bureau will communicate this report to designated Offices in accordance with Rules 44 <i>bis</i> .3(c) and 93 <i>bis</i> .1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44 <i>bis</i> .2).																								

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No. +41 22 740 14 35	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 2px;">Date of issuance of this report 16 January 2006 (16.01.2006)</td> </tr> <tr> <td style="padding: 2px;">                     Authorized officer   <div style="text-align: center; font-weight: bold;">Yoshiko Kuwahara</div> </td> </tr> <tr> <td style="padding: 2px;">Telephone No. +41 22 338 90 90</td> </tr> </table>	Date of issuance of this report 16 January 2006 (16.01.2006)	Authorized officer  <div style="text-align: center; font-weight: bold;">Yoshiko Kuwahara</div>	Telephone No. +41 22 338 90 90
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Authorized officer  <div style="text-align: center; font-weight: bold;">Yoshiko Kuwahara</div>				
Telephone No. +41 22 338 90 90				

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:  
SCOTT E. KAMHOLZ  
FOLEY HOAG LLP  
155 SEAPORT BLVD.  
BOSTON, MA 02210

**PCT**

REC'D 13 MAY 2005

WIPO

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## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference MAA-011.25		Date of mailing (day/month/year) <b>11 MAY 2005</b>
FOR FURTHER ACTION See paragraph 2 below		
International application No. PCT/US04/21247	International filing date (day/month/year) 02 July 2004 (02.07.2004)	Priority date (day/month/year) 11 July 2003 (11.07.2003)
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61M 37/00, 1/14 and US Cl.: 604/4.01, 6.14; 422/44, 45		
Applicant BRIGHAM AND WOMEN'S HOSPITAL		

**1. This opinion contains indications relating to the following items:**

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application


**2. FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

**3. For further details, see notes to Form PCT/ISA/220.**

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer  Patricia M. Bianco Telephone No. (571) 272-4940
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**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US04/21247

**Box No. I Basis of this opinion**

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/US04/21247

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>5, 11, 16, 17, 22</u>	YES
	Claims <u>1-4, 6-10, 12-15, 18-21, 23-44</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-44</u>	NO
Industrial applicability (IA)	Claims <u>1-44</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-4, 6-10, 12-15, 18-21, & 23-44 lack novelty under PCT Article 33(2) as being anticipated by Sterman et al. (US 6,027,476). Sterman discloses an apparatus and method that has a heart bypass system for placing a patient on bypass, performing a cardiac procedure, and an endoscope/angioscope that is connected to the patient for perfusing the heart with a non-impairing fluid medium to visualize the heart. The endoscope/angioscope will inherently be connected to a fluid source via tubing, thereby constituting a circuit.

Claims 4-6, 11, 16, 17, & 22 lack an inventive step under PCT Article 33(3) as being obvious over Sterman et al. (US '476). Sterman does not explicitly teach that either the first or second circuits receive blood or pumping medium from a vena cava for return to the aorta, where the medium is a fluorocarbon, such as perfluorocarbon, and that the observation is of a heart valve. However, it would have been obvious to modify the circuits to use the vena cava and aorta to deliver fluids, since it is commonly done in perfusion methods. It also would have been obvious to perform the surgical procedure that includes visualization of heart valves. With respect to the medium being a fluorocarbon, such as perfluorocarbon, these fluids are well known in the art as perfusate.